

**DOCKET NO.: ARC2366N2/ALZA-0143**  
**Application No.: 10/645,715**  
**Office Action Dated: January 26, 2005**

**PATENT**  
**REPLY FILED UNDER EXPEDITED**  
**PROCEDURE PURSUANT TO**  
**37 CFR § 1.116**

## **REMARKS**

Claims 32 to 48 are pending in this patent application. No claims have been amended, canceled, or added, herein. Applicants respectfully request reconsideration of the rejections of record in view of the following remarks.

### **Alleged Double Patenting**

Claims 32 to 48 have been rejected under the judicially created doctrine of obviousness-type double patenting as allegedly unpatentable over the claims of various patents and a patent application. Applicants request deferral of the rejections pending the identification of allowable subject matter, as they can likely be readily resolved (depending upon the subject matter ultimately allowed) through the filing of suitable terminal disclaimers.

### **Alleged Obviousness**

Claims 32 to 39 have been rejected under 35 U.S.C. § 103(a) because the claimed subject matter allegedly would have been obvious to those of ordinary skill in the art in view of an abstract of JP 406009388A, assigned to Kodama KK (“the Kodama abstract”). Applicants respectfully traverse the rejection because the Kodama abstract fails to teach or suggest all of the limitations recited in the claims.

Claims 32 to 39 recite dosage forms that deliver oxybutynin and salts thereof at a substantially zero order rate of release over a period of about 24 hours.

Although the Kodama abstract describes sustained release oxybutynin hydrochloride pharmaceutical preparations, it fails to mention a rate of release of the oxybutynin hydrochloride from the preparations, much less describe delivery of oxybutynin hydrochloride at a substantially zero order rate of release over a period of about 24 hours. Accordingly, the rejection for alleged obviousness is improper and should be withdrawn. *In re Royka*, 490 F.2d 981, 180 U.S.P.Q. 580 (C.C.P.A. 1974) (all limitations set forth in a patent claim must be taught or suggested in the prior art to establish a prima facie case of obviousness).

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Although the Examiner asserts that “the limitation of zero order rate of release is met by the prior art” (Office Action at page 3), the Office Action fails to identify any evidence supporting this assertion. Absent such support, the assertion does not constitute evidence of the type that is required to support the instant rejection. *In re Zurko*, 258 F.3d 1379, 1386 (Fed. Cir. 2001)(evidence of record required to support assertion that the cited prior art teaches all the limitations recited in the claims).

The Office Action is also mistaken with respect to its suggestion (Office Action at page 3) that Applicants’ claims lack clarity because they do not expressly recite all of the ingredients and additives that can potentially be used in the claimed dosage forms. The standard for clarity in patent claims of the type at issue here is satisfied so long as one skilled in the art is able to determine whether a dosage form of interest falls within the claims’ scope. *In re Mercier*, 185 U.S.P.Q. 774 (C.C.P.A. 1975) (claims are definite so long as one skilled in the art can determine their scope). Not only does the Office Action fail to allege that those skilled in the art would have been unable to make this determination, but it is well established that details such as specific ingredients need not be recited in the claims. M.P.E.P. §2164.08, citing *W.L. Gore & Assoc., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1558, 220 U.S.P.Q. 303, 316-17 (Fed. Cir. 1983) (“One does not look to the claims but to the specification to find out how to practice the claimed invention.”). Thus, there is no basis for the Office Action’s suggestion that the pending claims are not clear.

Simply put, Applicants’ claims are directed to dosage forms that release oxybutynin and its pharmaceutically acceptable salts at a substantially zero order rate over a period of about 24 hours. The Kodama abstract fails teach or suggest such dosage forms. Accordingly, the rejection should be withdrawn.

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**Conclusion**

Applicants believe that the foregoing constitutes a complete and full response to the Office Action of record. An early and favorable action is therefore respectfully requested.

Respectfully Submitted,

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